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15 **UNITED STATES DISTRICT COURT**
16 **DISTRICT OF ARIZONA**

17 Richard Di Donato, Individually and
18 On Behalf of All Others Similarly
19 Situated,

20 Plaintiff,

21 v.

22 Insys Therapeutics, Inc.; Michael L.
23 Babich; Darryl S. Baker; John N.
24 Kapoor; and Alec Burlakoff

25 Defendants.

No. 16-cv-302-NVW

**DEFENDANTS' MOTION TO
DISMISS AND MEMORANDUM
OF POINTS AND AUTHORITIES**

**ORAL ARGUMENT
REQUESTED**

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Defendants Insys Therapeutics, Inc., Michael L. Babich, Darryl S. Baker, John N. Kapoor and Alec Burlakoff move to dismiss Plaintiff Clark Miller’s Second Amended Class Action Complaint (the “Complaint”) for failure to state a claim, pursuant to Rules 9 and 12(b)(6) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u *et seq.* (“PSLRA”).

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiff filed the Second Amended Complaint on December 22, 2016, primarily to add allegations relating to the indictment of Babich, Burlakoff and other Insys employees on December 8, 2016. Plaintiff, however, continues to attack the same alleged misstatements outlined in his prior amended complaint and still alleges the same basis for securities fraud: Insys’s supposed failure to disclose that Company employees provided kickbacks, marketed an Insys product for unapproved uses and committed fraud against insurance companies. But, in fact, Insys disclosed both: (1) the risk that such conduct could occur, and (2) the fact that Insys was under investigation for such conduct—long before Plaintiff or other putative class members bought shares of the Company. In addition to Insys’s disclosures, the same information was also reported widely in the national news media.

Although the fact of the indictment was new information, many of the allegations it contained already had been publicized. Further, it did not correct any prior alleged misstatements. Indeed, Plaintiff’s theory that Insys investors were defrauded is inconsistent with other positions he has taken in this case. Plaintiff previously argued that the “truth” about Insys was revealed between November 2014 and April 2016, when investors supposedly learned that the Company was allegedly an “active criminal enterprise” and that “prosecutors [were] moving aggressively in their investigation”. (ECF No. 67 at p. 2, 27 (brackets in original).) Plaintiff’s Complaint now alleges that it was the indictment that caused investors to learn that “Insys was engaged in a multi-year nationwide criminal scheme”. (Compl. ¶ 23.) If investors learned the “truth” about the

Company's alleged criminal activity in April 2016, they could not have continued to be misled about this activity between April 2016 and December 2016 when the indictment was announced. In an effort to increase alleged damages, Plaintiff has identified a series of stock drops over a more than two year period, but has failed to identify, with the specificity required by the securities laws, what particular information was concealed from investors and how the disclosure of such information caused him loss. The Complaint should be dismissed.

II. STATEMENT OF FACTS

Insys manufactures and sells Subsys, a fentanyl product indicated for the treatment of breakthrough pain (*i.e.*, an intense increase or flare of otherwise stable and persistent pain) experienced by opioid-tolerant adults with cancer. (*See* Compl. ¶¶ 1, 2.)¹ Plaintiff alleges that the Company's financial statements and other statements made by Defendants from August 12, 2014 through December 8, 2016 (the "Class Period") were false and misleading because Defendants failed to inform investors that the Company was engaged in an illegal kickback scheme, off-label marketing of Subsys and fraud against health insurance companies. (*See, e.g.*, Compl. ¶¶ 12-15.) But the indisputable evidence appropriate for a motion to dismiss shows that, during and even long before the Class Period, the information Plaintiff claims the Company should have disclosed had already been in the public domain. *First*, the Company had already disclosed that it was under federal investigation for such misconduct. *Second*, before the Class Period, lawsuits with the same allegations had been filed against the Company, and the national news media had criticized the Company for alleged illegal marketing of its product. *Finally*, even before the Company disclosed actual allegations of kickbacks and off-label marketing, Insys repeatedly warned investors of the risk that such improper conduct might occur.

¹ On a motion to dismiss, courts may consider "the complaint, materials incorporated into the complaint by reference, and matters of which the court may take judicial notice". *See Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1061 & 1064 n.7 (9th Cir. 2008).

A. The Company's Legal and Regulatory Problems Were Publicly Disclosed Before the Class Period Began.

On May 2, 2013, over a year before any members of the putative class bought Insys stock, Insys explicitly informed investors of risks that could adversely affect the Company's financial performance, including specifically that the Company's "employees may engage in misconduct or other improper activities" and that the Company could be subject to regulatory actions for failing "to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws", which prohibit kickbacks and the submission of false claims. (Ex. 1 at 30, 43-44.)² This warning was repeated or reaffirmed in every subsequent quarterly or annual report filed by the Company, before and during the Class Period. (Exs. 2-13.)

In July 2013, still over a year before the Class Period, a *Qui Tam* Complaint asserting that the Company had violated federal and state False Claims Acts was unsealed. (Ex. 14.) The relator, a former sales professional at the Company, alleged that the Company: (i) provided kickbacks to physicians in exchange for prescribing Subsys, (ii) promoted off-label usage of Subsys, and (iii) improperly encouraged physicians to prescribe Subsys at higher dosages than indicated by the FDA-approved label. (*Id.* ¶¶ 88-113.) The relator specifically alleged that he personally had witnessed Michael Babich and Alec Burlakoff, who were then the Company's CEO and Vice President of Sales, respectively, participate in misconduct. (*Id.* ¶ 101.)

On December 13, 2013, eight months before the Class Period, the Company issued a press release disclosing to investors that the Office of the Inspector General of the Department of Health and Human Services ("HHS") was investigating potential violations related to the Company's sales and marketing practices for Subsys. (Ex. 15.)

² All "Ex." references herein are to the Exhibits to the Declaration of Nicole Sornsin, which is Exhibit A to Defendants' Request for Judicial Notice in Support of the Motion to Dismiss the Amended Class Action Complaint, filed contemporaneously with this Motion.

1 On May 13, 2014, three months before the Class Period, *The New York Times*
 2 published an article entitled “Doubts Raised About Off-Label Use of Subsys, a Strong
 3 Painkiller”, which characterized the Company’s marketing practices as aggressive and
 4 potentially improper, and which referenced the then-recent arrest of a Michigan doctor
 5 charged with Medicare fraud in connection with prescriptions of Subsys. (Ex. 16.)

6 On May 15, 2014 and May 19, 2014, still three months before the Class Period,
 7 two putative securities class actions were filed against the Company in this District.
 8 (Ex. 17; Ex. 18 (collectively, the “Prior Securities Complaints”).) The Prior Securities
 9 Complaints, repeating allegations in the earlier *Qui Tam* Complaint, alleged that between
 10 May 1 or 2, 2013 to May 8, 2014, the Company made false and misleading statements
 11 indicating that its strong financial performance was attributable to a motivated sales force
 12 and the quality of its Subsys product, when in fact the Company’s performance was
 13 driven by off-label marketing of Subsys, kickbacks and efforts to persuade doctors to
 14 prescribe the medication at higher-than-indicated dosages. (*See* Ex. 17, ¶¶ 6, 23-35;
 15 Ex. 18, ¶¶ 7, 22-33, 42-44.)

16 According to the Prior Securities Complaints: “(i) the Company engaged in illegal
 17 and/or unethical off label marketing of Subsys; (ii) the Company was exposed to
 18 potential fines and other disciplinary actions as a result of its Subsys marketing practices;
 19 and (iii) as a result, the Company’s financial statements were materially false and
 20 misleading at all relevant times.” (Ex. 17, ¶ 6; *see also* Ex. 18, ¶ 7.) The Prior Securities
 21 Complaints allege that when the “truth” was revealed in a series of negative filings and
 22 news articles, the price of shares of common stock in Insys dropped, causing harm to the
 23 putative class members. (Ex. 18, ¶¶ 46, 34-35; Ex. 17, ¶¶ 36-41.) The first disclosure
 24 was the December 12, 2013 Form 8-K disclosing the subpoena from HHS. (Ex. 17,
 25 ¶¶ 36-37.) The second disclosure was a May 8, 2014 Michigan local news report of a
 26 criminal complaint charging a Michigan doctor with Medicare fraud in connection with
 27 his prescriptions of Subsys. (Ex. 17, ¶¶ 38-39; Ex. 18, ¶¶ 34-35.) And the third
 28 disclosure was a May 11, 2014 report by an analyst highlighting the allegations against

the Michigan doctor. (Ex. 17, ¶¶ 40-41.)³

B. The Company Continued Warning Investors During the Time Plaintiff Alleges Information Was Concealed.

1. Plaintiff Alleges That the “Truth Behind Subsys’s Success” Began to Be Revealed Even Before He Purchased Any Stock.

The Class Period begins in August 2014, when Insys reported its financial results for the second quarter of 2014. Plaintiff alleges this report began a “fraudulent scheme to mislead investors” concerning the factors that affected Subsys sales. (Compl. ¶¶ 11, 13.) Plaintiff also alleges, however, that “[t]he truth behind Subsys’s success” began to be revealed almost immediately after the publication of these results. (Compl. Section IV.D.)

On September 12, 2014, near the beginning of the Class Period, after having informed investors nine months earlier of an HHS investigation into the Company’s sales and marketing practices, the Company disclosed publicly that the U.S. Attorney’s Office for the District of Massachusetts was conducting an investigation concerning the Company’s sales and marketing practices for Subsys. (Ex. 20.) Despite the additional multiple public disclosures discussed above, Plaintiff alleges that *this* disclosure was the one that began the revelation of “[t]he truth behind Subsys’s success”. (Compl. ¶ 315.) Although it was this U.S. Attorney’s Office that ultimately pursued the indictment against Babich and Burlakoff in 2016, the disclosure of the U.S. Attorney’s investigation revealed nothing materially different from the Company’s disclosure nine months earlier that a federal investigation was underway. (*Compare* Ex. 15 with Ex. 20.)

On November 27, 2014, *The New York Times* published an article entitled “Using Doctors with Troubled Pasts to Market a Painkiller”. (Compl. ¶ 316; Ex. 21.) The article

³ On October 27, 2014, plaintiffs in the prior securities litigation filed an amended complaint (the “Prior Amended Securities Complaint”), which refers to a confidential witness who allegedly worked as a “Prior Authorization (PA) specialist” and allegedly witnessed improper conduct. (Ex. 19, ¶¶ 84-86.) The consolidated class action litigation based on the Prior Amended Securities Complaint was settled on May 28, 2015. *Larson v. Insys Therapeutics, Inc.*, 14-cv-0143, Dkt No. 66 (D. Ariz.).

1 reported that three doctors received payments through Insys’s speaker program and “were
 2 said to have inappropriately prescribed painkillers”. (Compl. ¶ 316; Ex. 21 at 2.) It also
 3 quoted from “former sales representatives” who reportedly said that “they were
 4 encouraged by the company to call on pain doctors . . . and to reward high-prescribing
 5 physicians with perks”. (Compl. ¶ 316; Ex. 21 at 3.) Most of the information in the
 6 article—including Insys’s prior disclosures that it had received subpoenas, reports about
 7 Insys’s aggressive marketing, and allegations of inappropriate physician prescription
 8 behavior—was repackaged from previous articles and public filings from before the
 9 Class Period. (See Exs. 15-18.) Nonetheless, Plaintiff alleges that the article “partially
 10 (but incompletely) revealed . . . Insys’ illegal promotion of Subsys for off-label use [and]
 11 illegal kickback payments”. (Compl. ¶ 400.)

12 On April 24, 2015, the *Southern Investigative Reporting Foundation* (“SIRF”)
 13 published an article entitled “Insys Therapeutics and the New ‘Killing It’”. (Ex. 22;
 14 Compl. ¶¶ 317-18.) The article referred to “data show[ing] that Subsys is proving lethal
 15 to a growing number of patients, many of whom . . . are taking it for so-called off-label
 16 indications”, and described the allegations in *The New York Times* articles, the *Qui Tam*
 17 Complaint and the Prior Amended Securities Complaint. (Ex. 22.) The article also
 18 discussed Heather Alfonso, a Connecticut-based nurse practitioner who surrendered her
 19 prescription-writing licenses during an investigation into her conduct related to Subsys,
 20 and noted that former Insys employees had been subpoenaed by the federal grand jury in
 21 Massachusetts or had been interviewed by HHS. (Ex. 22 at 11.)

22 Despite all of this negative public information about Insys that Plaintiff himself
 23 alleges revealed the “truth” about the Company, Plaintiff made his first purchase of
 24 nearly \$15,000 of stock after this information was disclosed on May 19, 2015. (Friedman
 25 Decl. Ex. A, ECF No. 34-1.)

26 2. Plaintiff Continues Purchasing Stock Even After More Allegedly
 27 “Corrective” Information Is Disclosed.

28 On May 20, 2015, the U.S. Attorney’s Office for the Southern District of Alabama

1 announced that two Alabama-based physicians had been indicted on healthcare fraud
 2 charges. (Compl. ¶ 319; Ex. 23.) Neither the press release nor the indictment mentioned
 3 Subsys or Insys. (*Id.*) And on June 23, 2015, Alfonso’s Information and Plea Agreement
 4 were entered onto the electronic docket in the U.S. District Court in Connecticut.
 5 (Compl. ¶ 321; Exs. 24-25.) As previously explained, news of the Alfonso investigation
 6 had already been public information. (*See supra* p. 6.) Subsequently, on June 25, an
 7 article published by *The New York Times* entitled “Nurse Pleads Guilty to Taking
 8 Kickbacks from Drug Maker”, reported on Alfonso’s guilty plea to receiving illegal
 9 payments in exchange for writing Subsys prescriptions. (Compl. ¶ 321; Ex. 26.) The
 10 article noted that the Company had “previously acknowledged that it [was] under federal
 11 investigation”, and linked to and repeated information from the two prior *New York*
 12 *Times* articles, including the one from before the start of the Class Period. (Ex. 26.)
 13 Nonetheless, Plaintiff alleges that these events “revealed some of the relevant truth . . .
 14 concerning Subsys”. (Compl. ¶¶ 408, 412.)

15 On June 8, 2015, Plaintiff sold all his shares for \$17,690, a *profit* of \$2,780.
 16 (Friedman Decl. Ex. A, ECF No. 34-1.) The next day, on July 9, 2015, Plaintiff
 17 purchased additional Insys stock. (Friedman Decl. Ex. A, ECF No. 34-1.)

18 3. Insys Continued To Provide Investors Current Information 19 Regarding Its Legal Matters.

20 Although not alleged by Plaintiff to be “corrective disclosures”, Insys provided
 21 investors current information about the continuing regulatory investigations during the
 22 time Defendants are alleged to have continued concealing facts about Insys. On
 23 August 5, 2015, the Oregon Attorney General’s Office announced that it had reached a
 24 settlement with Insys to resolve allegations that Insys had marketed Subsys off-label and
 25 provided improper financial incentives to doctors to increase Subsys prescriptions.
 26 (Ex. 27.) In the settlement, Insys did not admit to any violation of law or regulation.
 27 (*See* Ex. 35 at 3.) The next day, in its quarterly filing, the Company informed investors
 28 of the Oregon settlement and that Alfonso had pleaded guilty to violating the federal

1 Anti-Kickback Statute in connection with payments of approximately \$83,000 from the
 2 Company. (Ex. 11 at 10-11.) The Company stated that it was investigating the matter.
 3 (*Id.*) In the same filing, the Company also informed investors that the offices of the
 4 Attorneys General of Arizona, Illinois and Massachusetts were each investigating the
 5 Company's sales and marketing practices. (Ex. 11 at 11.)

6 4. Plaintiff Alleges That Five More Disclosures "Partially Corrected"
 7 Prior Fraudulent Statements.

8 Plaintiff then alleges several "partial corrective disclosures" around the date of
 9 Insys's third quarter 2015 financial results. On November 4, 2015, the day before Insys
 10 released its third quarter financial results, CNBC published an article entitled "The pain
 11 killer: A drug company putting profits above patients". (Compl. ¶¶ 415-17; Ex. 28.)
 12 The article, written with the assistance of the author of the prior SIRF article, relied on
 13 the Prior Amended Securities Complaint, past reporting by SIRF, the Company's public
 14 filings, the Oregon settlement, the Alfonso plea and unnamed sources to describe the
 15 conduct that was alleged in those prior sources. (Ex. 28.) The article also stated that
 16 HHS had placed Subsys on a list of "new diversion drugs of concern", indicating that
 17 Subsys may have been prescribed for unintended uses. (Ex. 28 at 2.) The next day, Insys
 18 announced its third quarter 2015 financial results and also disclosed that Defendant
 19 Babich was resigning from his position as CEO and that Defendant Kapoor had been
 20 appointed President and CEO of the Company. (Compl. ¶ 325; Exs. 29-30.)⁴

21 SIRF published two additional articles on December 3, 2015 and January 25, 2016
 22 that Plaintiff alleges were also "partial corrective disclosures". (Compl. ¶¶ 423, 427.)
 23 The December article, entitled "Murder Incorporated: Insys Therapeutics, Part I", cited
 24 anonymous sources to allege that Michael Babich had been forced to resign by Kapoor
 25 and that the Company was operating an illegal kickback scheme to promote off-label
 26

27 ⁴ On January 9, 2017, the Company announced that Kapoor had retired as Chairman,
 28 President and CEO of the Company. (Ex. 49.)

1 marketing of Subsys. (Compl. ¶ 326; Ex. 31.) The January article, entitled “The
2 Brotherhood of Thieves: Insys Therapeutics”, alleged that the Company was continuing
3 to engage in improper off-label marketing of Subsys. (Compl. ¶ 330; Ex. 32.) Both
4 articles cited and quoted from the prior articles and filings. (Exs. 31-32.)

5 Plaintiff’s prior amended complaint alleged that the final “corrective disclosure”
6 occurred on April 11, 2016, when Insys announced that its first quarter 2016 revenues
7 would be lower than expected. (Compl. ¶ 432.) The announcement, however, said
8 nothing about off-label marketing or kickbacks.

9 Between April and December 2016, investors learned of additional events
10 concerning the Company: (1) the arrest of a former District Manager and a former sales
11 representative for allegedly providing kickbacks in June 2016 (Compl. ¶ 337), (2) a
12 complaint against the Company by the State of Illinois in August 2016 containing similar
13 allegations previously made by other governmental entities (Compl. ¶ 338), (3) the arrest
14 of a former District Sales Manager for allegedly providing kickbacks in September 2016
15 (Compl. ¶ 339), (4) a letter from a U.S. Senator to the Administrator of the Centers for
16 Medicare and Medicaid Services, allegedly raising concerns about Medicare coverage for
17 Subsys, which was sent in October 2016 (Compl. ¶ 340), and (4) the arrest of a former
18 Manager of Reimbursement Services in October 2016 for allegedly conspiring to defraud
19 health insurance companies (Compl. ¶ 341), and (5) the guilty plea by a physician who
20 had prescribed Subsys to healthcare fraud and unlawful prescription of Subsys for no
21 legitimate medical purpose, in November 2016 (Compl. ¶ 342).

22 Although Plaintiff alleges that these events were part of the way in which “the
23 truth behind Subsys’s success [was] slowly revealed”, they are not alleged to have caused
24 investors any loss. Plaintiff instead alleges that on December 8, 2016, as a result of the
25 indictment, investors finally “learned that Insys was engaged in a multi-year nationwide
26 criminal scheme, orchestrated and executed by the Company’s highest-ranking
27 executives, to increase revenues from selling Subsys” from the “very illegal payment of
28 kickbacks to prescribers and insurance fraud” Plaintiff alleges had been revealed since

2014. (Compl. ¶ 435.)

III. ARGUMENT

Although the Court assumes, for purposes of a motion to dismiss, that all factual allegations in the complaint are true, “the court need not . . . accept as true allegations that contradict matters properly subject to judicial notice or by exhibit. Nor is the court required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences.” *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001) (citations omitted).

Plaintiff’s claim for securities fraud should be dismissed in its entirety because it fails to plead sufficiently a misrepresentation or omission of a material fact and loss causation. The Complaint also fails to plead scienter against Kapoor and Baker, and several elements of a securities fraud claim against Burlakoff.

A. Plaintiff’s Section 10(b) Claims Should Be Dismissed.⁵

1. The Complaint Fails To Plead Actionable False or Misleading Statements.

Plaintiff’s Second Amended Complaint relies on the same alleged misstatements as his prior complaint. Those remain inactionable for the same reasons presented in Defendants’ prior motion to dismiss, and the new allegations do not affect that analysis. To allege claims for securities fraud, the complaint must allege that a defendant made a *false statement*—“an untrue statement of a material fact”—or a *misleading statement*—a statement that omits “a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading”. 15 U.S.C. § 78u-4(b)(1)(A)-(B). The complaint must plead with particularity “each statement alleged to have been misleading” and “the reason or reasons why the statement is misleading”. 15 U.S.C. § 78u-4(b)(1). Although Plaintiff consistently conflates these two concepts

⁵ In the prior amended complaint, Plaintiff added a new Defendant, Alec Burlakoff. Because Burlakoff is alleged only to have made misstatements attributed to him by a single article, the arguments for dismissal of the claim against him are presented separately at the end of this Memorandum. (*See infra* pp. 29-30.)

1 throughout the Complaint by alleging that statements were “false and misleading” (*see*,
 2 *e.g.*, Compl. ¶¶ 172, 179, 189, 195, 201), they are distinct, and Plaintiff fails to plead any
 3 misstatements with the particularity required, or explain *why* any statements were either
 4 false *or* misleading. Plaintiff also challenges forward-looking statements, which are
 5 inactionable as a matter of law.

6 (a) The Complaint Does Not Plead With Particularity Why the
 7 Challenged Statements, Taken in Context, Are False or
Misleading.

8 Plaintiff challenges three categories of statements as “false and misleading”, none
 9 of which are properly pled. *First*, the Complaint challenges statements concerning the
 10 financial results, historical sales, growth, profitability and marketing strategy for Subsys.⁶
 11 Plaintiff does not allege that any of this financial information (*e.g.*, revenue or growth
 12 numbers) was actually false. In addition, Plaintiff does not allege that the reasons
 13 provided for the growth of Subsys revenues—the “successful execution” of the
 14 Company’s strategy, “a clinically superior product”, “change in the mix of prescribed
 15 dosages” or that Subsys “helps” patients—were not, in fact, factors that affected revenue.

16 Plaintiff also alleges that the Company’s statements that it marketed Subsys by
 17 “building awareness among oncologists” and that the Company had “some very unique
 18 programs in the oncology setting”, both in March 2015, were false. (Compl. ¶¶ 268,
 19 272.) Plaintiff relies on the allegation that Burlakoff instructed sales representatives “to
 20 avoid meeting with oncology doctors and pain specialists” at a national sales meeting
 21 sometime in 2014 (Compl. ¶¶ 113, 275), but that does not mean that the Company did not
 22 make efforts to educate oncologists about Subsys at the time these statements were made
 23 in 2015.⁷

24 ⁶ (Compl. ¶¶ 251, 254, 260-62, 267-68, 271-72, 282-84, 292, 297-98, 300-01, 309.)

25 ⁷ Relatedly, Plaintiff confuses the issue by alleging that it was somehow improper for
 26 the Company to focus marketing efforts on physicians who already prescribed other
 27 drugs in the same class as Subsys, all of which are approved only for BTCP, which is a
 28 strategy that was previously disclosed to investors. (Compl. ¶¶ 115-17.) But physicians
 who prescribe drugs in the TIRF class (including Actiq and Subsys) are required to enroll
 in the restrictive TIRF REMS program mandated by the FDA. (Ex. 50.) Physicians who

As for being misleading, the Complaint alleges that each of these statements was “false and misleading” because the Company failed to disclose that Subsys revenues “were the result of Insys’s illegal promotion” or of “wide-ranging, pervasive insurance fraud”.⁸ The Ninth Circuit, however, “has consistently held that the PSLRA’s falsity requirement is not satisfied by conclusory allegations that a company’s class period statements regarding its financial well-being are *per se* false based on the plaintiff’s allegations of fraud generally”. *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1070 (9th Cir. 2008). In *Metzler*, the plaintiff alleged that the company’s purported “fraudulent practices” rendered its public statements about its “financial well-being” “either affirmatively false or false by way of omission” (*i.e.*, misleading). *Id.* The court held that the allegation in a complaint of fraud was insufficient to render a company’s public statements false *or* misleading for failing to disclose that supposed fraud. *Id.* at 1070-71 (rejecting the notion that “statements regarding [a company’s] financial status were false because they ‘create the false impression that defendants ran their business with proper financial reporting compliance’”). Plaintiff’s allegations here are similarly generalized as those found to be insufficiently pled in *Metzler* and accordingly cannot be the basis for a securities fraud claim.

Further, and most importantly, none of the Company’s statements could have been misleading because the Company explicitly disclosed that the conduct that Plaintiff

enroll in the TIRF REMS must review an Education Program concerning TIRFs and their approved use, successfully complete a Knowledge Assessment and acknowledge their understanding that, although they are not precluded from prescribing TIRFs for other uses, TIRFs are indicated only for breakthrough cancer pain. (Ex. 50.) And although the manufacturer of Actiq had pled guilty to off-label marketing in 2008, the manufacturer had entered into a Corporate Integrity Agreement that imposed extensive remedial measures concerning its interactions with physicians and required an independent monitor to review its compliance with those measures, negating any assumption that, years later, Actiq prescribers remained tainted by off-label marketing. (Ex. 51.) Plaintiff also acknowledges that some insurers require that patients try Actiq before using Subsys. (Compl. ¶ 270.) For all these reasons, it is not plausible to infer that marketing to Actiq prescribers necessarily constituted off-label marketing.

⁸ (See Compl. ¶¶ 257, 264, 274, 286, 294, 304, 310.)

claims the Company concealed was being investigated and challenged in civil proceedings. *See In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1414 (9th Cir. 1994) (referring to the “unremarkable proposition that statements must be analyzed in context”). The Company never denied or misled investors about any investigation, but rather informed investors of specific law enforcement investigations into the very type of employee misconduct about which the Company had warned since going public in 2013.⁹ *Cf. Metzler Inv.*, 540 F.3d at 1071 (concluding that *failing to disclose* regulatory investigations did not render defendant company’s public statements about revenue and growth false or misleading because the connection between the statements and the investigations was “extraordinarily vague”). In addition, in each SEC filing since Insys went public, the Company informed investors of the significant risks associated with employee misconduct in marketing and sales practices and other activity in the highly regulated industry in which the Company operates.¹⁰ Investors were informed of these risks by each of the Company’s public filings starting *before the Class Period*. (Exs. 1-13.) Specifically, investors were expressly warned “our employees may engage in misconduct or other improper activities” including “intentional failures to comply with FDA regulations . . . [and] with federal and state healthcare fraud and abuse laws and regulations” and that “[e]mployee misconduct could also involve . . . illegal promotion of a drug product for off-label use”. (Ex. 5 at 41; *see also, e.g.*, Ex. 2 at 38; Ex. 9 at 39.) In light of this and other similar repeated disclosures, Defendants’ statements were not misleading as a matter of law because the allegedly omitted information was made public both by Insys and by others.

Second, the Complaint challenges statements concerning the Company’s interactions with healthcare insurers. (*See* Compl. ¶¶ 252-53, 261, 269-70, 284, 293, 302,

⁹ (Ex. 7 at 12; Ex. 8 at 10-11; Ex. 9 at 84-85; Ex. 10 at 11-12; Ex. 11 at 10-11; Ex. 12 at 10-11; Ex. 13 at 85-86; Ex. 15; Ex. 35 at 4.)

¹⁰ (Ex. 1 at 30, 38-39, 43-44; Ex. 2 at 38, 44-45, 48; Ex. 3 at 27; Ex. 4 at 25; Ex. 5 at 41, 46-48; Ex. 6 at 27; Ex. 7 at 29; Ex. 8 at 29; Ex. 9 at 22, 39, 43-46; Ex. 10 at 29; Ex. 11 at 29-30; Ex. 12 at 30; Ex. 13 at 36, 40-42.)

303, 313.) The Complaint repeatedly alleges that those statements were “false and misleading” because Defendants failed to disclose that Subsys revenues were the result of “the creation and utilization of” an Insurance Reimbursement Center (also known as the Patient Services Center or “IRC”) “to surreptitiously engage in wide-ranging, pervasive insurance fraud”. (*See, e.g.*, Compl. ¶ 257.)

When examined in context, many of the statements challenged by Plaintiff are not only not “false”, but have nothing to do with the IRC. For example, Defendant Babich stated that “We continue to proactively work with managed care providers to ensure coverage”. (Comp. ¶ 252.) The plain meaning of this statement, expressed in the very next sentence of the disclosure cited by Plaintiff, is that the Company had worked to “maintain Tier 3 coverage under nearly all major insurance plans”—*i.e.*, to ensure that insurance plans covered Subsys in the first place, not to ensure that they granted prior authorizations. (Compl. ¶ 252.) Similarly, Defendant Babich’s statement that “we continue to properly communicate with all the major plans and the [pharmacy benefit managers] to ensure proper access for Subsys” also referred to the Company’s efforts to ensure Subsys would remain covered by health insurance plans. (Ex. 34 at 9; Compl. ¶ 12.) The statements made about the IRC—such as that the IRC was created to “provide administrative patient support assistance”—are not false because Plaintiff does not allege that the IRC does not exist or did not actually provide such assistance. (*See* Compl. ¶¶ 212, 269, 284, 293, 302.)

All this leaves Plaintiff with the argument that the statement was misleading because the statement omitted that the IRC’s “true purpose” was “defrauding third-party payers into approving insurance coverage for off-label prescriptions of Subsys”. (*E.g.*, Compl. ¶ 212.) Plaintiff cannot base his securities fraud claim, however, on the allegation that general statements about the Company left the misimpression that its performance was due to “legitimate business means that could be expected to continue”. *See Metzler Inv.*, 540 F.3d at 1057, 1071. Moreover, before and throughout the Class Period, in many of the Company’s disclosures challenged as misleading, investors were

1 given prominent, specific information concerning the risk of employee misconduct (*see*
 2 Ex. 5 at 41; *see also, e.g.*, Ex. 2 at 38; Ex. 9 at 39), as well as the heightened regulatory
 3 risks posed by the Company’s utilization of an insurance reimbursement support hub,
 4 including that it is “subject to extensive and complex federal and state laws” and that
 5 “companies that violate such laws, regulations and standards may face substantial
 6 penalties”. (*See, e.g.*, Ex. 9 at 24; Ex. 8 at 29; Ex. 7 at 17.) In light of these express
 7 disclosures, the challenged statements could not have been misleading because they
 8 omitted a statement of the risk of misconduct involving the IRC.

9 *Third*, the Complaint challenges as “false and misleading” statements made later
 10 in the Class Period about the Company’s investigation into employee misconduct, and its
 11 policies and procedures relating to compliance.¹¹ These statements were not false. For
 12 example, Plaintiff challenges as “false and misleading” the Company’s statement in a
 13 press release and earnings call that the Company was “committed to complying with
 14 laws”. (Compl. ¶¶ 289, 291.) But these statements were made in the context of the
 15 Company announcing its settlement of claims with the Oregon Department of Justice,
 16 and simply described the Company’s future goals (Ex. 35 at 3; Ex. 36 at 6). Thus, they
 17 are not rendered false or misleading by allegations of past misconduct. Similarly,
 18 Plaintiff challenges the statement in the Company’s Form 10-Q that the Company had
 19 “taken a number of remedial actions and implemented enhancements to the Company’s
 20 compliance controls regarding relationships with health care providers”, but would
 21 “continue to assess these matters to ensure we have an effective compliance program”.
 22 (Compl. ¶ 303; Ex. 12 at 11.) Plaintiff does not allege that the Company did not take
 23 remedial actions, nor does Plaintiff allege that Insys stopped assessing its compliance
 24 program or stopped working to make it effective. Similarly, the Company’s statement in
 25 January 2016 that it was “striv[ing] to comply with applicable laws and regulations” and
 26 required its personnel to “undergo specific training on applicable laws and regulations”
 27 (Compl. ¶ 313) is not rendered untrue by allegations that employees had earlier engaged

28 ¹¹ (*See* Compl. ¶¶ 278, 289, 291, 303, 309, 313.)

1 in misconduct.

2 Further, these statements were not misleading because none was a guarantee that
 3 the risk of employee misconduct had been eliminated; rather, each was accompanied by
 4 disclosures of the very risks Plaintiff alleges were omitted. Throughout the Class Period,
 5 including in the very documents Plaintiff cites for these alleged misleading statements,
 6 the Company provided and referenced warnings about the risk of employee misconduct.
 7 (See Ex. 35 at 4 (citing the “Risk Factors” in the Company’s public filings, which
 8 included the risk of employee misconduct); Ex. 36 at 1 (citing risks noted in the press
 9 release and public filings); see, e.g., Ex. 5 at 41 (disclosing the risk of employee
 10 misconduct); Ex. 2 at 38 (same); Ex. 9 at 39 (same).)¹² Finally, to the extent Plaintiff
 11 alleges that such statements are misleading for failing to disclose the purported ongoing
 12 fraud, that type of allegation is, again, insufficient as a matter of law. See *Metzler Inv.*,
 13 540 F.3d at 1071.

14 (b) Forward-Looking Statements Are Protected by the Statutory
 15 Safe Harbor.

16 Many of the statements challenged by Plaintiff are “forward-looking statements”
 17 that cannot form the basis of a claim under the securities laws.¹³ The PSLRA provides a
 18 “safe harbor” for “forward-looking statements” if the statement is “identified as a
 19

20 ¹² Plaintiff alleges that Defendant Kapoor’s statement concerning Babich’s reasons
 21 for resigning in November 2015 was false and misleading, because it concealed that
 22 Babich “had been forced out as a result of the intensity and focus of multiple related
 23 regulatory investigations”. (Compl. ¶ 306.) However, the regulatory investigations were
 24 never concealed from investors but instead were fully described in multiple disclosures
 25 throughout the Class Period. In his prior briefing, Plaintiff argued that the statement was
 26 misleading because it “concealed that Kapoor fired Babich due to his role in the
 27 misconduct being investigated” (ECF No. 67 at p. 16 n.9), but Plaintiff’s Complaint
 28 contains no particular allegations supporting that argument and only alleges that Kapoor
 caused Babich to resign because “‘Babich was closest to the issues’ under investigation
 and that a change was necessary to appease government regulators” (Compl. ¶ 326), not
 that he was “fired” due to misconduct. The indictment, which came more than a year
 after Babich resigned, also could not have rendered Kapoor’s statement false when made.

¹³ (See Compl. ¶¶ 251, 267, 268, 269, 282, 284, 293, 297, 298, 302, 303.)

1 forward-looking statement, and is accompanied by meaningful cautionary statements
 2 identifying important factors that could cause actual results to differ materially from
 3 those in the forward-looking statement” *or* plaintiffs do not plead that the statement was
 4 made “with actual knowledge” that the statement was false or misleading. 15 U.S.C.
 5 § 78u-5(c)(1); *see In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111-13 (9th Cir. 2010).

6 For example, Plaintiff alleges that it was false and misleading when Defendant
 7 Babich stated on a March 3, 2015 earnings call that “I think Q4 is a great indication of
 8 what we can do with the product moving forward as well. . . . I’ve always talked about,
 9 from a market share, our next total is 50% market share. . . . So I think long term we can
 10 eventually get to that 60% market share for this product.” (Compl. ¶ 268.) Plainly, when
 11 “examined as a whole, the challenged statement[] relate[s] to future expectations and
 12 performance”. *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051,
 13 1059 (9th Cir. 2014).

14 This and the other forward-looking statements are in the “safe harbor” because
 15 they were identified as forward-looking statements and were accompanied by meaningful
 16 cautionary statements in every SEC filing, press release and earnings announcement cited
 17 by the Complaint.¹⁴ In addition, the Company informed investors in its SEC filings that
 18 there were “important factors that could cause actual results to differ materially from
 19 those in the forward-looking statement[s]”. 15 U.S.C. § 78u-5(c)(1)(A); *see Police Ret.*
 20 *Sys.*, 759 F.3d at 1058. In particular, the Company expressly warned investors of the
 21 same regulatory and compliance risks Plaintiff now erroneously contends were
 22 concealed. (*See, e.g.*, Ex. 9 at 22, 39, 43; *see also* Exs. 10-12.) When forward-looking
 23 statements are accompanied by such cautionary statements, the statements cannot be used
 24 as the basis of a securities law claim as a matter of law. *See In re Cutera*, 610 F.3d at
 25 1112.

26 ¹⁴ (*See* Ex. 9 at 39, 43, 57; Ex. 10 at 17, 29; Ex. 11 at 16-17, 29-30; 17-18, 29; Ex. 29
 27 at 2; Ex. 30 at 4; Ex. 33 at 1-2; Ex. 35 at 5; Ex. 37 at 2-3; Ex. 38 at 3; Ex. 39 at 3-4;
 28 Ex. 40 at 5; Ex. 41 at 4-5; Ex. 42 at 4-6; Ex. 43 at 4-5; Ex. 44 at 5-6; Ex. 45 at 4; Ex. 46
 at 4.)

2. The Complaint Fails to Plead Loss Causation.

As in the first Amended Complaint, the Plaintiff still fails to sufficiently plead another essential element of a securities fraud claim: loss causation. In *Dura Pharmaceuticals*, the Supreme Court made clear that plaintiffs must plead a causal link between alleged misrepresentations and actual economic loss by alleging that the revelation of the misrepresentation caused the price of the security to decrease. *Dura Pharmaceuticals, Inc., v. Broudo*, 544 U.S. 336, 342-46 (2005). Accordingly, with the particularity required by Rule 9(b) and the PSLRA, Plaintiff must “allege specific statements . . . that were made untrue or called into question by subsequent public disclosures”. *Oregon Pub. Emp. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 608 (9th Cir. 2014).

In Plaintiff’s first Amended Complaint, he merely tracked stock price drops and then deemed whatever event occurred that day a “partial corrective disclosure”, even if it contained no new news that undermined prior statements. For the same reasons discussed in Defendants’ prior motion to dismiss, this approach does not sufficiently plead loss causation. Plaintiff’s Second Amended Complaint differs only in that it adds the indictment of Babich and Burlakoff on December 8, 2016, as an additional, final corrective disclosure, and alleges that as a result of the indictment, investors finally “learned that Insys was engaged in a multi-year nationwide criminal scheme, orchestrated by the Company’s highest-ranking executives”. (Compl. ¶ 23.) But the fact of this new allegation means that none of the alleged “partial corrective disclosures” prior to December 2016 could have constituted “new news” that rendered untrue an alleged misstatement. Indeed, Plaintiff previously argued that investors learned that Insys was an “active criminal enterprise” by April 2016. (ECF No. 67 at p. 2.) Plaintiff cannot argue coherently both that investors learned this alleged “truth” about Insys between August 2014 and April 2016, and that the “truth” was finally revealed only in December 2016 as a result of the indictment.

Many of the so-called partial corrective disclosures repeat allegations that were

1 contained in the *Qui Tam* Complaint or in the Prior Securities Complaints and, thus, were
 2 not new news. For example, the SIRF articles extensively quote or paraphrase
 3 allegations contained in the *Qui Tam* and Prior Securities Complaints, including
 4 allegations concerning kickbacks, off-label marketing of Subsys and efforts to persuade
 5 physicians to prescribe a higher-than-indicated dose. (Exs. 22, 31.) The Prior Securities
 6 Complaints, which were filed in 2014 long before the Class Period, were obviously
 7 known to the market. Indeed, the Company specifically disclosed the underlying
 8 litigations in its August 12, 2014 Form 10-Q and in subsequent SEC filings. (Exs. 7-13.)
 9 The Prior Securities Complaints, in turn, repeated many of the allegations from the earlier
 10 *Qui Tam* Complaint that had become public well before the beginning of the Class
 11 Period.

12 Examining each alleged “partial corrective disclosure” further demonstrates that
 13 Plaintiff has failed to plead with the requisite particularity how any of the alleged
 14 disclosures contained new news that “made untrue or called into question” any of the
 15 alleged misstatements. *See Apollo Grp.*, 774 F.3d at 608. The first two events—the
 16 November 27, 2014 *New York Times* article and the April 24, 2015 SIRF article—were
 17 published prior to Plaintiff’s stock purchases in May and July 2015, and therefore could
 18 not have caused his loss. (Compl. ¶¶ 399, 403.) Despite Plaintiff’s conclusory assertion
 19 that the *New York Times* article revealed an “illegal kickback scheme” (Compl. ¶ 399),
 20 the article does not reveal the existence of such a scheme, but rather focuses on individual
 21 doctors and sales representatives. (Ex. 21). Plaintiff admits as much when he notes that
 22 the article describes a practice that investors would only “later learn” was an unlawful
 23 kickback scheme. (Compl. ¶ 399.)

24 Moreover, the only portion of the SIRF article that Plaintiff particularly claims
 25 was a corrective disclosure—a government investigation that the Company disclosed
 26 publicly on September 2014 (Compl. ¶¶ 403-04; Ex. 22)—has been rejected by the Ninth
 27 Circuit as insufficient, without more, to plead loss causation. *See Loos v. Immersion*
 28 *Corp.*, 762 F.3d 880, 890 (9th Cir. 2014) (“While the disclosure of an investigation is

1 certainly an ominous event, it simply puts investors on notice of a *potential* future
2 disclosure of fraudulent conduct. Consequently, any decline in a corporation’s share
3 price following the announcement of an investigation can only be attributed to market
4 speculation . . . [and] cannot form the basis of a viable loss causation theory.”).

5 The third event—a May 20, 2015 announcement that two doctors were indicted
6 for unlawfully distributing unspecified Schedule II controlled substances—does not
7 mention Insys, Subsys or any off-label marketing or kickback scheme. (Compl. ¶¶ 407-
8 09; Ex. 23.)

9 The fourth event was the June 23, 2015 guilty plea by Heather Alfonso and a *New*
10 *York Times* article about the plea two days later. (Compl. ¶¶ 411-13; Exs. 24-26.)
11 Plaintiff points to nothing specific in either statement that disclosed new information
12 about the Company. Instead, he merely repeats that these events “revealed new
13 information that was previously concealed”. (Compl. ¶¶ 408, 412.) Plaintiff’s only
14 attempt at specificity is an allegation that the *New York Times* article states that the
15 “guilty plea was a signal that prosecutors were intensifying their investigation of the
16 Company’s marketing practices”. (Compl. ¶ 411.) But this is the *New York Times*’s
17 speculation, and, as explained, an investigation, “simply puts investors on notice of a
18 *potential* future disclosure of fraudulent conduct” and is “insufficient to establish loss
19 causation”. *See Loos*, 762 F.3d at 890. Furthermore, the revelation that an individual
20 was punished for misconduct is not analogous to a disclosure of Company-wide unlawful
21 conduct. *See Metzler Inv.*, 540 F.3d at 1063 (investigation of one campus out of 88 was
22 not a revelation of a for-profit university’s company-wide scheme).

23 The fifth event was the publication of a *CNBC* article on November 4, 2015.
24 (Compl. ¶¶ 415-17.) Plaintiff claims that this article disclosed that Subsys was placed,
25 presumably alongside other drugs, on an internal HHS list of “new diversion drugs of
26 concern”, where “diversion is defined as ‘a form of medical fraud that can include
27 doctors prescribing drugs for unintended uses’”. (Compl. ¶ 415.) However, HHS’s
28 labeling Subsys a diversion drug is not a disclosure that the Company had been engaged

1 in off-label marketing or a kickback scheme. Rather, as Plaintiff himself alleges, this
2 label only means that doctors might be prescribing the drug for unintended uses (Compl.
3 ¶ 415), or, as another of Plaintiff's sources indicates, means that Subsys is "the most
4 frequently stolen or fraudulently obtained" (Ex. 31 at 3). None of these accusations
5 revealed that any prior statement by any Defendant was false or misleading.

6 The sixth supposed disclosure was the resignation of Babich on November 5,
7 2015. (Compl. ¶¶ 419-21.) Unsurprisingly, Plaintiff points to no particular disclosure
8 that arose out of Babich's resignation, as there was nothing revealed except the fact that
9 Babich was resigning. (Compl. ¶ 419.) Furthermore, although Plaintiff is correct that the
10 stock price dropped from \$26.38 to \$25.43 between November 4 and November 5, by the
11 end of trading on November 6, the price had not only recovered, but had increased to
12 close at \$27.39¹⁵, negating any plausible inference that the resignation had revealed
13 information that caused a loss to Plaintiff. *See Metzler Inv.*, 540 F.3d at 1064.

14 The seventh and eighth events were SIFR articles on December 3, 2015 and
15 January 25, 2016, which Plaintiff claims revealed that Insys's "prior authorization unit"
16 provided false information to pharmacy benefit managers so that they would cover
17 Subsys. (Compl. ¶¶ 423-31; Exs. 31, 32.) But those allegations were recycled from the
18 Prior Amended Securities Complaint, which was filed on October 27, 2014, and which
19 even refers to a confidential witness who allegedly worked in the "prior authorization
20 unit" and witnessed improper conduct. (Ex. 19, ¶¶ 84-86.) Plaintiff also alleges that,
21 contrary to Kapoor's November 5, 2015 statement, the December 3, 2015 SIFR article
22 revealed that Babich had been forced to resign because of the various government
23 investigations into the Company. (Compl. ¶¶ 423-24.) However, this quote attributed to
24 an anonymous "senior Insys executive" is wholly unreliable, and there is no allegation
25 that Babich resigned because of a Company-wide off-label marketing or kickback
26 scheme. Rather, the anonymous executive states only that Kapoor said that Babich had to
27 resign because he was "closest to the issues that federal prosecutors were looking at and

28 ¹⁵ See <http://www.nasdaq.com/symbol/insy/historical>.

1 that a change had to be made should settlement talks become serious”. (Ex. 31 at 1;
2 Compl. ¶¶ 326, 382.)

3 The ninth alleged event is a Company press release announcing net revenues on
4 April 11, 2016, which Plaintiff alleges were lower than expected. (Compl. ¶¶ 332, 432-
5 34.) However, the press release itself does not reveal anything about an alleged off-label
6 marketing or kickback scheme. (Ex. 33.) Moreover, an announcement of lower earnings
7 is not an implicit corrective disclosure of a fraudulent scheme that forms a basis for loss
8 causation. *See Metzler Inv.*, 540 F.3d at 1064-65 (rejecting announcement of lower
9 earnings as implicit disclosure of an underlying fraudulent scheme). Although the
10 Company’s stock price dropped after the April 11, 2016 announcement, the “far more
11 plausible reason for the resulting drop” was not fraud, *see id.* at 1065, but is admitted in
12 Plaintiff’s own allegations: “revenues [were] significantly lower than consensus
13 expectations” (Compl. ¶ 432).

14 Finally, Plaintiff now alleges that it was only in December 2016 when investors
15 learned “that Insys was engaged in a multi-year nationwide criminal scheme, orchestrated
16 and executed by the Company’s highest-ranking executives, to increase revenues from
17 selling Subsys”. (Compl. ¶ 435.) Although the indictment of the Company’s former
18 CEO and others is undeniably a significant, new event affecting the Company, Plaintiff
19 still has failed to identify with the required particularity any alleged misstatement that
20 was rendered untrue by this disclosure, and consequently has failed to allege loss
21 causation with respect to this disclosure as well. *See Apollo Grp.*, 774 F.3d at 608.

22 In the alternative, Plaintiff invokes the “materialization of the risk theory”. (*See*,
23 *e.g.*, Compl. ¶¶ 428-30.) Under that theory, a plaintiff may plead loss causation, without
24 a “corrective disclosure”, by alleging that a risk materialized that was “within the zone of
25 risk *concealed* by the misrepresentations and omissions”. *Nuveen Mun. High Income*
26 *Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1120 (9th Cir. 2013) (internal
27 citation omitted). However, “[t]he Ninth Circuit has not adopted the materialization of
28 the risk approach” for loss causation. *Id.* at 1122 n.5. Although some district courts in

1 this Circuit have experimented with the theory, the Court of Appeals more recently
 2 required that plaintiffs allege “specific statements made by the Defendants that were
 3 made untrue or called into question by subsequent public disclosures” and rejected less
 4 particularized showings of loss causation. *See Apollo Grp.*, 774 F.3d at 608.

5 Moreover, even if Ninth Circuit courts applied the materialization of risk theory,
 6 the theory is not adequately pled here and requires dismissal of Plaintiff’s Complaint. To
 7 the extent that Plaintiff alleges that Defendants concealed the risk of government
 8 investigations or legal actions or negative publicity concerning the Company’s sales and
 9 marketing practices (*e.g.*, Compl. ¶¶ 400, 404), none of those risks was ever concealed at
 10 any time; each was fully disclosed starting from before the Class Period. (*Supra* p. 13.)
 11 The theory is also not pled adequately with respect to the indictment of Babich, Burlakoff
 12 and other employees, because the risk that Company employees would be accused of
 13 misconduct had been fully disclosed (by the Company and by the media) before and
 14 during the Class Period and was not concealed. (*Supra* p. 13.)

15 **B. The Complaint Fails to Plead Facts Giving Rise to a “Strong**
 16 **Inference” of Scienter on the Part of Kapoor and Baker, and the**
 17 **Claims Against Them Should Be Dismissed.**

18 The PSLRA requires a complaint to “state with particularity facts giving rise to a
 19 *strong inference* that the defendant acted with the required state of mind” (*i.e.*, scienter).
 20 15 U.S.C. § 78u-4(b)(2) (emphasis added). “To qualify as ‘strong’ . . . an inference of
 21 scienter must be more than merely plausible or reasonable—it must be cogent and at least
 22 as compelling as any opposing inference of nonfraudulent intent.” *Tellabs, Inc. v. Makor*
 23 *Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). For most misstatements, Plaintiff points
 24 to the same paragraphs of the Complaint to allege that all sets of financial results, as well
 25 as the earnings calls and press releases that went with them, were false and misleading.
 26 (*See* Compl. ¶¶ 257-58, 264-65, 274-75, 277, 276-87, 294-95, 304-06, 310, 314 (citing
 27 Compl. ¶¶ 90-249, 348-396).) These paragraphs largely consist of inappropriate “group”
 28 pleading that fails to give rise to a strong inference of scienter. The paragraphs that refer
 to Kapoor or Baker also fail to plead facts giving rise to a strong inference of scienter.

1 Importantly, the indictment of Babich and Burlakoff does not refer to or contain
 2 allegations concerning Kapoor or Baker; the more compelling inference to be drawn from
 3 the allegations—sufficient to defeat scienter under the securities laws—is that Kapoor
 4 and Baker were not aware of the misconduct alleged in the indictment and in Plaintiff’s
 5 Complaint. *See Tellabs*, 551 U.S. at 308.

6 (a) Plaintiff’s Inappropriate Group Pleading Fails to Plead Facts
 7 Giving Rise to a Strong Inference of Scienter.

8 The majority of Plaintiff’s scienter allegations lump “Defendants” together
 9 without distinguishing among them. (*See* Compl. ¶¶ 359-75, 380-81.) These allegations
 10 fail to connect Kapoor or Baker to scienter for specific misstatements. *See Apollo Grp.*,
 11 774 F.3d at 607.

12 Further, Plaintiff’s group allegations fail to plead facts giving rise to a strong
 13 inference of scienter. Plaintiff alleges that “Defendants”’ senior positions, hands-on
 14 management, and involvement in the day-to-day activities of the Company establish
 15 scienter. (Compl. ¶¶ 359-60.) It is well-settled, however, that allegations of scienter
 16 based on a defendant’s role as senior management are insufficient. *See Metzler Inv.*, 540
 17 F.3d at 1068. Similarly, Plaintiff’s allegation that “Defendants” had access to
 18 information (Compl. ¶¶ 364-75) is also insufficient to establish scienter. *See Lipton v.*
 19 *Pathogenesis Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002); *South Ferry*, 542 F.3d at 783
 20 (concluding that plaintiffs must “bridge the gap” between a defendant’s mere access to
 21 information and an inference of knowledge).

22 Plaintiff also attempts to rely on the “core operations” exception, which would
 23 allow the Court to draw a strong inference of scienter based on the principle that
 24 “corporate officers have knowledge of the critical core operations of the company”.
 25 *Police Ret. Sys.*, 759 F.3d at 1062. The Ninth Circuit has held repeatedly, however, that
 26 the core operations exception can by itself establish scienter only “in rare circumstances
 27 where the nature of the relevant fact is of such prominence that it would be absurd to
 28 suggest that management was without knowledge of the matter”. *Id.* (citing *S. Ferry LP*,

1 *No. 2 v. Killinger*, 542 F.3d 776, 785-86 (9th Cir. 2008)). For example, the Ninth Circuit
2 has drawn a strong inference of scienter when the defendants failed to disclose stop-work
3 orders from its largest customers, which had a “devastating effect” on the company’s
4 revenues and were “disastrous for the entire company”. *South Ferry LP, No. 2 v.*
5 *Killinger*, 542 F.3d 776, 785 n.3. (9th Cir. 2008) (citing *Berson v. Applied Signal*
6 *Technology, Inc.*, 527 F.3d 982, 983, 988 (9th Cir. 2008)). It is insufficient to allege that
7 Defendants “should have known” the information undermining their statements, because
8 only information they “must have known” is “sufficient to meet the strict scienter
9 pleading requirements”. *See Glazer*, 549 F.3d at 748.

10 Plaintiff asserts that “Defendants” should be deemed to have knowledge of all the
11 circumstances concerning the marketing of Subsys, primarily based on Subsys
12 representing more than 98% of the Company’s revenues (Compl. ¶ 362) and a statement
13 by Kapoor on December 1, 2015 that he and unnamed executives at Insys reviewed the
14 number of Insys prescriptions written each day as the Company competed for market
15 share (Ex. 47 at 3; Compl. ¶ 363; *see also* Compl. ¶¶ 359-75). Plaintiff’s argument,
16 however, “rests on a[] [flawed] inference that the [daily tracking of prescriptions]
17 mutually excludes the possibility that [Defendants] were unaware of [alleged unlawful
18 conduct]”. *Metzler Inv.*, 540 F.3d at 1067-68 (rejecting allegations that because senior
19 management was “regularly made aware of . . . enrollment and placement figures”, they
20 must have known about alleged fraudulent practices related to those figures); *Zucco*
21 *Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1000-01 (9th Cir. 2009), *as amended*
22 (Feb. 10, 2009) (explaining that the fact “management analyzed the inventory numbers
23 closely, do[es] not support the inference that management was in a position to know that
24 such data was being manipulated”).

25 Plaintiff’s own allegations, moreover, are inconsistent with the theory that it
26 would be “absurd” for Defendants not to be aware of a company-wide scheme to commit
27 unlawful conduct. For example, Plaintiff relies on a source who says that sales training
28 was “by the book, exactly like Merck or someone might do”, but that “district and

1 regional managers”—not senior management—would later tell sales associates to “just
2 sell”. (Compl. ¶ 128.) Such allegations of concealed misconduct by junior employees
3 actually cut against Kapoor and Baker’s alleged scienter.

4 Plaintiff alleges that government investigations, criminal charges and guilty pleas
5 by individual Insys employees demonstrate that the “Defendants” as a group all had
6 scienter when they made the alleged statements. (Compl. ¶¶ 383-85.) But none of these
7 events included facts indicating that any Defendant had any prior knowledge of any
8 unlawful conduct. Moreover, the Company had consistently disclosed all government
9 investigations. (Exs. 7, 20.) Government investigations into company conduct alone do
10 not demonstrate that specific individuals had scienter, *see Thorpe v. Walter Inv. Mgmt.,*
11 *Corp.*, 111 F. Supp. 3d 1336, 1376 (S.D. Fla. 2015), especially because Kapoor and
12 Baker were not among those who were indicted.

13 Finally, Plaintiff alleges that “Defendants’ Incentive Compensation” is a fact
14 giving rise to a strong inference of scienter. (Compl. ¶¶ 394-96.) Not only is such an
15 allegation plainly insufficient, *see In re Tibco Software, Inc. Secs. Litig.*, 2006 WL
16 1469654 at *21 (N.D. Cal. May 24, 2006); *In re Rigel Pharmaceuticals, Inc. Secs. Litig.*,
17 697 F.3d 869, 884 (9th Cir. 2012) (“it is common for executive compensation, including
18 stock options and bonuses, to be based partly on the executive’s success in achieving
19 corporate goals”), but Plaintiff’s allegations only mention Baker, and thus cannot give
20 rise to an inference with respect to Kapoor (Compl. ¶¶ 394-96).

21 (b) Plaintiff’s Individualized Allegations Fail to Plead Facts
22 Giving Rise to a Strong Inference of Scienter.

23 In addition to the insufficient group allegations, Plaintiff has also provided a few
24 individualized allegations of scienter. None is sufficient to give rise to the strong
25 inference required under the PSLRA for Kapoor or Baker.

26 **Kapoor.** Kapoor was the Co-Founder and Chairman of Insys and became the
27 CEO on November 5, 2015. (Compl. ¶ 348.) Plaintiff ignores this change in Kapoor’s
28 role and erroneously treats statements made by Kapoor after he became CEO as if they

1 relate to the entire Class Period and thus can be proven false by allegations concerning
2 only the pre-November 2015 time period. For example, Plaintiff alleges that Kapoor's
3 November 5, 2015 statement that "we only call on REMS doctors" (*i.e.*, doctors who
4 have already qualified to prescribe Subsys and other TIRFs under the FDA's REMS
5 program) was false (Compl. ¶ 298) because of allegations that, before Kapoor became
6 CEO, sales representatives called upon physicians who had not prescribed TIRFs. (*E.g.*,
7 Compl. ¶¶ 112 (citing pre-November 2015 allegations).) And Kapoor could not have
8 intended this statement to mislead investors because his purpose in making it was to warn
9 them that, because of this limitation on the Company's marketing efforts, "further growth
10 is going to be slower than in the past" (Compl. ¶ 298), not to conceal that Subsys
11 revenues would continue to grow only as a result of misconduct, as Plaintiff alleges was
12 Defendants' motive throughout his Complaint. Similarly, the fact that Kapoor stated,
13 after he became CEO, that he and other executives monitored the number of prescriptions
14 written for Subsys "every single day" (Compl. ¶ 349) does not establish his knowledge of
15 falsity of any statement at all, much less for any statements made before he became CEO.
16 Plaintiff's failure to show that Kapoor knew statements were false *when made* precludes
17 both falsity and scienter with respect to him.

18 Further, unattributed hearsay statements in news articles in which anonymous
19 sources allege that Kapoor was "behind all this greed", "built this whole thing", and
20 forced Babich to resign because he was "closest to the issues that federal prosecutors
21 were looking at" (Compl. ¶¶ 350, 382), are not sufficient, because such anonymous
22 hearsay statements are not facts that can support an inference of scienter. *See Zucco*
23 *Partners*, 552 F.3d at 997 (hearsay statement from anonymous finance employee is
24 insufficient to establish scienter); *Constr. Laborers Pension Trust of Greater St. Louis v.*
25 *Neurocrine Biosciences, Inc.*, 2008 WL 2053733, at *6 (S.D. Cal. May 13, 2008)
26 (anonymous witness's statement that company vice president knew that certain
27 information was incorrect was insufficiently reliable to establish scienter).

28 Plaintiff's allegation that "on information and belief" only, Kapoor knew that

1 Insys was representing the “effective dose” of Subsys as between 600 and 1600 mcg—
 2 allegedly contrary to its label—is belied by the actual allegations of the Illinois State
 3 complaint from which it is drawn. (Compl. ¶ 131). That complaint makes clear that the
 4 Insys Board is alleged to have known that the Company was educating physicians that “3
 5 out of 4 patients found an effective dose between 600 and 1600 mcg” (Ex. 52), not that
 6 the Company “defined” the effective dose as “600 mcg to 1600 mcg”, as represented by
 7 Plaintiff. (Compl. ¶ 131.)

8 Plaintiff also alleges that Kapoor’s understanding of FDA regulations and rules
 9 gives rise to a strong inference of scienter. (Compl. ¶ 351.) However, the allegation that
 10 Kapoor knows the rules, absent the allegation of *facts* showing that Kapoor had
 11 knowledge of activities that violated those rules, does not give rise to a strong inference
 12 of scienter. Finally, Plaintiff alleges, without any explanation, that the Company’s use of
 13 a restaurant owned by Kapoor to hold events (Compl. ¶ 148), and a third-party text
 14 message alleging that Kapoor advocated recruiting physicians to join the speaker
 15 program, as is generally lawful (Compl. ¶¶ 123-24), somehow demonstrate scienter.
 16 Similarly, the allegation that Kapoor attended a dinner at which the Company agreed to
 17 sell Subsys directly to two prescribers (Compl. ¶ 194) does not indicate that Kapoor knew
 18 the Company allegedly had a separate, unlawful arrangement to provide those doctors
 19 kickbacks. And the *only* allegation concerning Kapoor’s alleged knowledge of the
 20 operations of the IRC unit is a second-hand account that he encouraged employees to
 21 obtain approvals for Subsys (Compl. ¶ 224), not that he knew of or condoned unlawful
 22 conduct to obtain those approvals. None of these allegations, individually or collectively,
 23 gives rise to *any inference*, let alone a strong inference, of scienter.

24 **Baker.** Baker was the CFO throughout the Class Period. (Compl. ¶ 355.) The
 25 Complaint provides practically no allegations in support of Baker’s scienter. Plaintiff
 26 attempts to allege a strong inference of scienter based on Baker’s position as CFO, his
 27 access to information, and his receipt of incentive-based compensation (Compl. ¶¶ 355,
 28 394-95), none of which come close to alleging scienter, as discussed previously.

Plaintiff's only other allegation against Baker relates to the Company's withholding of 5% of his potential bonus in 2015. (Compl. ¶ 396.) It is implausible that Insys would reduce Baker's bonus by only 5% because it had learned Baker had engaged in unlawful conduct. Indeed, as the Company's proxy statement makes clear, the Company withheld 5% of "each named executive officer[s]" bonus because "notwithstanding the largely positive metrics[,] . . . the Company needed to improve in 2016 in instilling a culture of accountability in all areas including research and development and regulatory and compliance matters." (Ex. 48 at 23 (2016 Proxy).) However, acknowledging the need to improve "instilling a culture of accountability" is a far cry from admitting knowledge of, or participation in, any long-running, company-wide scheme that Plaintiff alleges.

C. Plaintiff's Claim Against Burlakoff Should Be Dismissed.

Burlakoff was the Vice President of Sales throughout the Class Period (Compl. ¶ 356) and is alleged to have made misstatements only in the April 24, 2015 SIRC report when he was quoted as allegedly stating that Insys was "selling a breakthrough cancer pain drug", that such pain was "all we want to address with a doctor" and that "no one at Insys wants to see anyone taking [Subsys] for anything other than cancer pain" (Compl. ¶¶ 278-79). Plaintiff's claims based on Burlakoff's statements must be dismissed for failure to allege that they were materially false or misleading or that the statements were made "in connection with" the purchase or sale of securities.

Burlakoff's statements in the SIRC report were not materially false or misleading. Plaintiff argues both that the SIRC report is a partial disclosure of the off-label marketing scheme *and* that it is the source of a misstatement for failing to disclose the very same scheme. (See Compl. ¶¶ 278-80, 403-05.) The remainder of the SIRC article—which implies that the Company was "killing it" financially and by placing patients at risk, and says that the company "is clearly in a lot of trouble"—could not have misled investors into believing that the Company had eliminated all employee misconduct. (Ex. 22 at 2, 4.) Read in the context of the entire report, Burlakoff's statements could not have been

1 materially misleading. *See Worlds of Wonder*, 35 F.3d at 1414.

2 Burlakoff's statements also are not actionable because Plaintiff does not allege
3 that they were made in a publication "on which an investor would presumably rely"—
4 e.g., in an SEC filing, press release, call with analysts or a financial news publication—or
5 were intended to influence the investing public. *SEC v. Rana Research, Inc.*, 8 F.3d
6 1358, 1362 (9th Cir. 1993). Therefore, Burlakoff's statements were not made in
7 connection with the purchase or sale of securities as required to establish liability under
8 the securities laws. *See In re Galena Biopharma, Inc. Sec. Litig.*, 117 F. Supp. 3d 1145,
9 1179 (D. Or. 2015). If Plaintiff did plead that investors relied on the content of this and
10 other SIRF articles, he would be forced to admit that investors already had extensive
11 information concerning the misconduct purportedly concealed by all Defendants' alleged
12 misstatements. Further, the Complaint does not allege that Burlakoff had any control
13 over the quote in the article. *See Raab v. General Physics Corp.*, 4 F.3d 286, 288-89 (4th
14 Cir. 1993) ("Without control over [the] report, any statement made by [company]
15 personnel could be taken out of context, incorrectly quoted, or stripped of important
16 qualifiers").¹⁶ These are independent reasons to dismiss the claims against Burlakoff.

17 **D. Plaintiff's Section 20(a) Claims Should Be Dismissed.**

18 To state a claim of "control person liability" under § 20(a), Plaintiff must allege:
19 (1) "a primary violation of federal securities law", and (2) that "the defendant exercised
20 actual power or control over the primary violator". *Zucco Partners, LLC*, 552 F.3d at
21 990 (internal citation omitted). Because Plaintiff fails to state a claim for a violation of
22 Section 10(b), Plaintiff's claim under Section 20(a) necessarily fails as well.

23 **IV. CONCLUSION**

24 For all the foregoing reasons, the Complaint should be dismissed, with prejudice.

25
26 ¹⁶ A separate but related point is that, because Burlakoff is not an officer of the
27 Company and did not have authority to make statements on behalf of the Company,
28 neither his scienter nor his alleged fraud may be attributed to the Company. *In re Energy Recovery, Inc. Sec. Litig.*, 2016 WL 324150, at *25 (N.D. Cal. 2016); *see also Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1576-78 (9th Cir. 1990).

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CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2017, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to the following CM/ECF registrants:

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